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Laurie Smaldone, M.D.
Regulatory Science & Outcomes Research

June 2, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm.1061
Rockville, MD 20852

Re: Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank
Docket No. 00D-1033, 65 Fed.Reg. 16620 (March 29, 2000)

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, beauty care, nutritionals and medical devices. We are a leading company in the development of innovative therapies for cardiovascular, metabolic, oncology, infectious diseases and neurological disorders.

The Bristol-Myers Squibb Pharmaceutical Research Institute (PRI) is a global research and development organization that employs more than 4, 300 scientists worldwide. PRI scientists are dedicated to discovering and developing best in class, innovative, therapeutic and preventative agents, with a focus on ten therapeutic areas of significant medical need. Currently, the PRI pipeline comprises more than 50 compounds under active development.

For these reasons, we are interested in and well qualified to comment on the FDA draft *Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank.*

General Comments

Bristol-Myers Squibb supports the policy of providing patients with serious or life threatening diseases with greater access to clinical trials of experimental therapies. The clinical trials data bank contemplated by section 113 of the Food and Drug Administration Modernization Act ("FDAMA") is a significant step towards implementing this policy. The information disseminated through the clinical trials data bank should be useful to patients, but should not compromise the proprietary nature of sponsor drug development programs. The database should also focus on providing information to patients who have the most urgent need for access to clinical trials of experimental therapies.

Specific Comments

Section IV of the draft Guidance addresses the identification of trials for a serious and life-threatening disease. The definition of the term "serious and life-threatening disease" is an important aspect to the implementation of section 113 of FDAMA. According to the draft guidance, "for purposes of responding to section 113 of the Modernization Act, sponsors should refer to the information about serious or life-threatening diseases provided in the guidance for industry on *Fast Track Drug Development Programs – Designation, Development, and Application Review.* " It would be helpful to all interested parties if the FDA clarified this reference. The implication is that the FDA interprets section 113 of FDAMA to mean that sponsors must submit information specifically on clinical trials for treatments that would qualify for fast track review under section 506 of the Federal Food Drug and Cosmetic Act (the "Act"). Bristol-Myers Squibb Company supports this position

because products that would be eligible for fast track review under section 506 of the Act are the products most urgently needed by patients. We believe that the intention of section 113 of FDAMA was to provide patients with greater access to clinical trials involving these specific products and that the databank should focus on these specific clinical trials.

Bristol-Myers Squibb Company appreciates the opportunity to provide comments to FDA on the draft guidance and respectfully requests that the Agency give consideration to our recommendations.

Sincerely,

Laurie F. Smaldone /JM Kenney

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